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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/522,373	03/10/2000	Lawrence A Loeb	16336-000730US	5107
20350	7590	02/13/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			LACOURCIERE, KAREN A	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/522,373	Applicant(s) LOEB ET AL.	
	Examiner Karen A. Lacourciere	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-18, 45-50 and 66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 and 45-50 is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6-9, 14 and 16 is/are rejected.
- 7) ☒ Claim(s) 2, 4, 5, 10, 12, 13, 15, 17 and 66 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

The objections to claims 7 and 18, set forth in the prior Office action, mailed 06-04-2003, are withdrawn in response to Applicant's amendments filed 10-31-2003.

Allowable Subject Matter

Claims 2, 4, 5, 10, 12, 13, 15, 17 and 66 are maintained as objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 18 and 45-50 are allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6- 9, 14 and 16 are maintained as rejected under 35 U.S.C. 102(b) as being anticipated by Larsen et al. (NAR, Vol 6, No. 4, April 1979).

Larsen et al. disclose administering an adenine analogue, Toyocamycin (TMC), to a murine cell line infected with the Friend virus, a murine retrovirus. They observe

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that the virions had a loss of infectivity during TMC treatment (see for example abstract) and further observe that TMC was incorporated into the RNA of the virion and a significant amount of virion sequences is lost (see for example page 1554) and, therefore, would be considered mutated.

Therefore, Larsen et al. anticipates claims 1, 3, 6-9, 14 and 16.

Response to Arguments

Applicant's arguments filed 10-31-2003 have been fully considered but they are not persuasive.

In response to the rejection of record of claims 1, 3, 6-9, 14 and 16 under 35 USC 102(b) as anticipated by Larsen et al. Applicant argues that the

In response to the rejection of record of claims 1, 3, 6-9, 14 and 16 under 35 USC 102(b) as anticipated by Larsen et al. Applicant argues that the methods disclosed by Larsen et al. speculate that the incorporation of Toyocamycin into viral RNA could possibly result in a miscoded message, but that the same research group later recanted this speculative conclusion. To support this argument Applicant cites Hamelin et al., which concludes that incorporation of Toyocamycin does not result in an altered reading frame, but acts through some other mechanism yet to be fully illustrated. Applicant argues that Larsen et al. does not meet all of the limitations of the claimed invention because the methods of Larsen et al. do not actually increase the mutation rate of a virus.

These arguments are not found to be persuasive because the methods disclosed by Larsen et al. comprise all of the methods steps of the instantly claimed methods and result in viral mRNA wherein Toyocamycin is incorporated into the RNA in place of adenosine and, therefore, all of the limitations of the claims are met. It is not clear from the results of Larsen et al. and Hamelin et al. that the mutation rate of the virus is not increased and, in fact, the observed incorporation of Toyocamycin in place of adenosine is a mutation. Additionally, in both of the references Larsen et al. and Hamelin et al., virally attributed RNAs migrating at unexpected positions on assay gels when cells were treated with Toyocamycin (see for example, page 490 of Hamelin et al.), which would be encompassed in the broad term of mutated sequences. Further, Larsen et al. use higher concentrations of Toyocamycin than Hamelin et al. (up to 1 $\mu\text{g/ml}$, whereas Hamelin et al. only goes as high as 0.5 $\mu\text{g/ml}$). Hamelin et al. does not provide an alternative mechanism for the viral inhibition activity of Toyocamycin and it does not eliminate the possibility of mutations, but rather states that Toyocamycin does not result in an altered reading frame (as opposed to, for example, point mutations). In both Larsen et al. and Hamelin et al. the assessment of mRNA is based only on quantity and neither references assesses individual mutations, beyond the determination of the incorporation of Toyocamycin, which in itself is a mutation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (571) 272-0759. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Lacourciere
February 9, 2004


KAREN A. LACOURCIERE, PH.D.
PRIMARY EXAMINER